JUL 24 2003

K032013

Summary of Safety and Effectiveness for COULTER® AcT™ 5diff Autoloader (AL) Hemalogy Analyzer with Version 1.10 Software

1.0 General Information

Device Generic Name(s): Automated differential cell counter

Device Trade Name(s): COULTER® AcT™ 5diff AL Hematology Analyzer

Device Classification: The COULTER® AcT™ 5diff AL Hematology Analyzer is a Class II medical device.

Applicant Name and Address: Beckman Coulter, Inc.
Cellular Analysis Division
11800 SW 147 Avenue
Miami, FL 33196-2500

Date: June 27, 2003

2.0 Legally Marketed Device(s)

The modified COULTER® AcT™ 5diff AL Hematology Analyzer with Version 1.10 Software claims substantial equivalence to the previously cleared COULTER® AcT™ 5diff AL Hematology Analyzer with Version 1.00 Software. FDA 510 (k) Number: K030291

The use of a second predicate device the COULTER® LH 750 Hematology Analyzer was used to show substantial equivalence of the extended Platelet Count linearity capability. FDA 510(k) Number: K022161.

3.0 Device Description

The Beckman Coulter, Inc. (BCI) Coulter® Ac•T™ 5diff Autoloader Hematology Analyzer (AcT™ 5diff AL) is a bench top laboratory instrument, designed for In Vitro diagnostic use in clinical laboratories.

The AcT™ 5diff AL provides automated complete blood counts (CBC) and leukocyte differential counts.

The following reagents, with 510(k) numbers indicated where applicable, are qualified for use on the COULTER® AcT™ 5diff AL Hematology Analyzer with Version 1.10 software:

Reagent	FDA Docket
COULTER® AcT™ 5diff Diluent – used in the dilution of blood for counting and differentiation of cells.	Class I Exempt
COULTER® AcT™ 5diff WBC Lyse – used to lyse RBC for WBC enumeration and differentiation	Class I Exempt
COULTER® AcT™ 5diff Fix – used to lyse RBC, fix and differentially stain WBC	Class I Exempt
COULTER® AcT™ 5diff Hgb Lyse – used to lyse RBC for hemoglobin determination	Class I Exempt
COULTER® AcT™ 5diff Rinse – enzymatic solution for rinsing	Class I Exempt

Calibrator and Control	FDA Docket
COULTER® AcT™ 5diff Control Plus control – manufactured and labeled for BCI by R&D Systems Inc.	K003534
COULTER® AcT™ 5diff Cal calibrator - manufactured and labeled for BCI by R&D Systems Inc.	K912357

4.0 Principle of Method:

The Beckman Coulter, Inc. (BCI) Coulter® Ac•T™ 5diff Autoloader Hematology Analyzer (AcT™ 5diff AL) is a bench top laboratory instrument, designed for In Vitro Diagnostic Use in clinical laboratories, capable of analyzing samples in a closed vial Autoloader mode or a Stat mode (open or closed vial).

The AcT™ 5diff AL provides automated complete blood counts (CBC) and leukocyte differential counts. The purpose of the AcT™ 5diff AL is to separate the normal patient, with all normal system-generated parameters from the patient who needs additional studies of any of these parameters. These studies might include further measurements of cell size, and or distribution, biochemical investigations, manual WBC differential or any other derivative test that helps diagnosis of the patient's condition.

The CBC analysis is based on the established Coulter Principle of automated cell counting and spectrophotometric hemoglobin determination.

The differential analysis uses the principles of aperture impedance, cytochemistry, focused flow impedance, and light transmission from a halogen light source.

The instrument is microprocessor driven with a PC that performs data processing and data management activities.

5.0 Indications for Use:

The COULTER® AcT™ 5diff AL hematology analyzer is a quantitative, automated hematology Analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories.

6.0 Description of the modification:

The currently marketed COULTER® AcT™ 5diff AL hematology analyzer with Version 1.00 software release was modified with software changes to improve performance characteristics and provide additional Workstation functionality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 24 2003

Ms. Lourdes Coba
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
Cellular Analysis Division
11800 SW 147 Avenue
Miami, FL 33196-2500

Re: k032013
Trade/Device Name: COULTER® AcT™ 5diff AL Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: June 27, 2003
Received: June 30, 2003

Dear Ms. Coba:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device: COULTER® AcT™ 5diff Autoloader (AL)

Indications For Use:

The COULTER® AcT™ 5diff AL Hematology Analyzer is a quantitative, automated hematology Analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories.

21 CFR 864.5220 Automated differential cell counter

An automated differential cell counter is a device used to identify and classify one or more of the formed elements of blood.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032013

(PLEASE DO NOT WRITE ~~BELOW THIS LINE-CONTINUE ON ANOTHER~~ PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109)